IN BRIEF

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Affymetrix patents defined

Aaron Bouchie

On January 22, a US District Court issued a Markman ruling defining the claims in DNA chip company Affymetrix's (Santa Clara, CA) patent infringement cases against database provider Incyte (Palo Alto, CA) and genomic-based biopharmaceutical company Hyseq (Sunnyvale, CA). Incyte and Hyseq allegedly both infringe two patents concerning physical DNA chip apparatus; additionally, Incyte is charged with infringing a fluorescent DNA detection method, while Hyseq is accused of infringing a computer-based system for determining the sequence of a DNA sample. The court did not narrow the claims of the patents—which means they could be deemed invalid if they are found to be too broad. However, general counsel Vern Norviel is confident about their validity, and has asked for an infringement trial as soon as possible; Affymetrix, which controls 90% of the DNA chip market, saw its stock soar nearly 20% to $70 in the week following the Markman ruling. Being found to infringe would be bad news for both Incyte and Hyseq: Incyte's database, which generated over 75% of its 2000 revenue, was built using the technologies in question, and Hyseq already received a $20 million credit line from its CEO George Rathmann on February 8 to combat dwindling cash reserves.

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Court Ruling Strengthens Affymetrix Patent Estate

- Favorable Markman Decision in Cases Against Hyseq and Incyte -

SANTA CLARA, Calif., Jan. 25 /PRNewswire/ -- Affymetrix, Inc. (Nasdaq: AFFX) announced today that the U.S. District Court for the Northern District of California issued a Markman ruling confirming the broad scope of four U.S. patents that Affymetrix has asserted in litigation against Incyte Genomics, Inc. (Nasdaq: INCY) and Hyseq, Inc. (Nasdaq: HYSQ). The Markman process is intended to provide early clarity to interpret the claims in a patent dispute.

Importantly, the patents have not been limited to photolithography, and have been construed to cover multiple methods of array fabrication, including synthesis and "spotting techniques." Specifically, the Court accepted Affymetrix' position that:

- Affymetrix array patents are not limited to arrays made by photolithography, but also cover arrays made by other manufacturing techniques;
- Affymetrix array patents are not limited to arrays containing nucleic acids that are synthesized in situ, but also cover arrays containing nucleic acids that are pre-formed and then deposited;
- Affymetrix assay patents broadly cover the detection of nucleic acids on arrays using multiple labels;
- Affymetrix software patents broadly cover computer programs that identify a base using hybridization.

"Today's Markman ruling strengthens these patents and solidifies our intellectual property portfolio. Our portfolio includes more than 100 issued, 36 allowed and over 300 pending patent cases in the U.S. alone," stated Vern Norviel, Senior Vice President and General Counsel of Affymetrix. "The ruling reinforces our cases against Incyte and Hyseq and we will move expeditiously to prove their infringement."

BACKGROUND

Today's Markman ruling interpreted patent Nos. 5,445,934 ('934), 5,744,305 ('305), 5,800,992 ('992), and 5,795,716 ('716) that have been asserted against Hyseq and Incyte.

Patents '934 and '305 are members of a patent family that covers arrays of more than 1000 oligonucleotides or at densities of more than 400 polynucleotides per square centimeter, respectively. The Court interpreted the '934 patent to include arrays containing oligonucleotides synthesized in situ as well as those pre-formed and then deposited on the arrays, stating that "the specification uses 'formation of a polymer' to mean both synthesis and immobilization of preformed polymers." The Court interpreted the '934 patent, one of the first to issue from this patent family, to cover oligonucleotides ranging in length from two to 100 nucleotides that are covalently joined to a solid surface.

The '305 patent was issued after the '934 and includes broader claims. Specifically, the Court found that '305 claims include polynucleotides of two nucleotides or more in length, whose sequence is either known or knowable and attached to a solid surface. The Court also agreed with the Affymetrix definition of "attached" to mean "secured or joined", covalently or not.

The Court found that a "discrete cell location" or "predefined region" implied activation using an energy source (as used by Incyte) for both the '934 and '305 patents, the United States Patent and Trademark Office has recently allowed additional claims in Affymetrix' patent applications without this limitation. The Court's interpretation combined with the recent notices of allowance establish that Affymetrix' family of array patents covers arrays made by a wide variety of techniques for in situ synthesis and deposition of pre-formed

polynucleotides.

Patent '992 is part of a "2-color" patent family which covers assays frequently used with DNA arrays. The Court found that the claims of '992 apply to using two different labels to detect "the presence or absence of two or more nucleic acid molecules" using hybridization. In construing Claim 1 of '992, the Court accepted Affymetrix' definitions that the method applies broadly to various types of genetic analysis on arrays including expression, genotyping and sequence detection. Only Claim 4 of the patent was limited by the Court to nucleic acid coming from two cell types.

Patent '716 is a member of one of Affymetrix' emerging software patent families. The Court interpreted claims in '716 to cover "a computer program product that identifies an unknown base in a sample nucleic acid sequence."

The Court rejected all of Hyseq's arguments, including their attempts to limit the claims of the '716 patent to the method described in the specification, and therefore upheld the full breadth of this patent.

Importantly, '716 covers a computer program to determine a nucleotide base using hybridization, independent of whether the hybridization is done on an array, beads or any other technology platform.

This Markman ruling did not construe claims of patent 6,040,193 ('193) or 5,871,928 ('928) that have been asserted by Affymetrix against Incyte. Patent '193 is a member of an Affymetrix instrument patent family covering spotting systems. Patent '928 is a member of an array family of patents directed to assays on arrays with densities of more than 100 per square centimeter.

Affymetrix is a leader in developing and commercializing systems to acquire, analyze and manage complex genetic information in order to improve the quality of life. The Company's GeneChip(R) system consists of disposable DNA probe arrays containing gene sequences on a chip, reagents for use with the probe arrays, a scanner, and other instruments to process the probe arrays and software to analyze and manage genetic information. The Company's spotted array system enables individual researchers to create and analyze custom microarrays on an easy-to-use, cost efficient platform. Additional information on Affymetrix and GeneChip technology can be found at www.affymetrix.com.

All statements in this press release that are not historical are "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act as amended, including statements regarding Affymetrix' "expectations," "beliefs," "hopes," "intentions," "strategies" or the like. Such statements are subject to risks and uncertainties that could cause actual results to differ materially for Affymetrix from those projected, including, but not limited to, uncertainties relating to technological approaches, product development, manufacturing, market acceptance, personnel retention, equity dilution, uncertainties related to the ability to realize benefits from acquisitions, uncertainties related to cost and pricing of Affymetrix products, dependence on collaborative partners, uncertainties relating to sole source suppliers, uncertainties relating to FDA and other regulatory approvals, competition, risks relating to intellectual property of others and the uncertainties of patent protection and litigation. These and other risk factors are discussed in Affymetrix' Annual Report on Form 10-K for the year ended December 31, 1999, and other SEC reports, including its Quarterly Reports on Form 10-Q for subsequent quarterly periods. Affymetrix expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Affymetrix' expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based. SOURCE Affymetrix, Inc

CONTACT: Edward M. Hurwitz, Vice President and Chief Financial Officer, 408-731-5000, or Anne Bowdidge, Director of Investor Relations, 408-731-5925, both of Affymetrix, Inc./

EXHIBIT T

D60

IN THE MATTER OF
European Patent No. 0 619 321
of Affymetrix Inc. and
Oppositions thereto

DECLARATION OF STEPHEN P.A. FODOR

I, Stephen P.A. Fodor, of 3380 Central Expressway, Santa Clara, California 95051, USA do solemnly and sincerely declare as follows:

1. I am the Chief Executive Officer and Chairman of the Board of Affymetrix Inc. ("Affymetrix"). I am a named inventor of European Patent 0 619 321. I have been closely involved with the development of the technology described in that Patent since 1989 and would consider that I have a good knowledge of that development.

2. It was clear to us in 1989 that the technique of using light to create high density arrays of diverse chemical entities could be applied to many different types of molecules including nucleic acids and others.

3. The initial commercial focus of Affymax was in the identification of targets and ligands as drug development compounds. I lead the development work, including the commercialisation of nucleotide arrays. The work that I and my group performed ultimately led to the establishment of Affymetrix in 1993 as a separate entity to Affymax.

Declaration of Dr. Michael Pirrung

4. I have seen the declaration of Dr. Michael Pirrung which I understand has been filed by an Opponent of the Patent. Unfortunately I disagree with much of what Dr. Pirrung says. To be able to explain why I disagree, it is important to describe Dr. Pirrung's involvement with the development of

the technology in the Patent and the subsequent development work carried out at Affymetrix to produce commercial DNA arrays.

5. Dr. Pirrung was already working at Affymax when I first began work there, and he and I shared an office. Dr. Pirrung contributed to the invention by way of identifying different molecules for use as photoprotective groups for polymers. In the time that I was at Affymax, and after filing of the first U.S. priority application, however, he was only superficially involved in experimental work and he did not play an active role in the day to day design or choice of experiments with nucleic acid arrays. His involvement in the research as a whole was largely superficial. He left Affymax towards the end of 1989, apparently to take up an academic position at Duke University.

6. Since that time, Dr. Pirrung has had only occasional contact with my research group at Affymax. He has not been involved with my research group in any experimental work to develop nucleic acid arrays at Affymetrix or Affymax.

7. In 1990, I began work on drafting a manuscript of our work for submission to a peer reviewed journal; the majority of the drafting was carried out by myself and Dr. Lubert Stryer. When we had completed a first draft of that paper, we sent a copy to Dr. Pirrung for his comments. Dr. Pirrung disagreed with the relative emphasis placed on different aspects of the paper. I had decided to include Dr. Pirrung as a co-author despite the fact that he had not been involved in the experimental work, as a professional courtesy. Although Dr. Pirrung had not been involved in the development work that made publication possible, he felt that he deserved a more prominent position than co-author and he suggested that he should be first or primary author. The manuscript was submitted in October 1990 and published in *Science* in February 1991. The paper was awarded the Newcomb Cleveland award for 1991 for the best paper to appear in

Science that year. Dr. Pirrung was clearly upset by my decision not to include him as the first author of the *Science* paper and I understand that he feels that my conduct has deprived him of the scientific recognition that he feels he deserved. For this and other reasons, since that time, my relationship with him has not been on the best of terms.

8. Dr. Pirrung has a history of borrowing research projects from Affymax or Affymetrix. For example, I understand that Dr. Pirrung applied for an NIH grant in 1991 to develop optimised photo-protecting groups for nucleotides, to investigate the use of different supports and to combine optimal supports, chemistry and photoremoveable groups. In fact, much of the optimisation work on photoremoveable protecting groups for nucleotides had already been done at Affymax and researchers in my group had already synthesised arrays of oligonucleotides well before that time. Even today we continue to work to optimise and improve our techniques for scientific and commercial reasons. This is, of course, perfectly normal for any developer or manufacturer of a new technology.

Moscow Conference

9. I have reviewed the notes of Dr. Paul Silverman describing his inferences from a talk I gave in November 1991 at the Sequencing by Hybridisation conference in Moscow. I have been asked to address the allegation that the Affymax technology could not be used to create arrays of oligonucleotides and that this was portrayed in my presentation.

10. To put the conference into context, in late 1991 interest in the Human Genome Project was becoming greater and scientists were seeking new methods to sequence the human genome cheaply and quickly. The proposal to sequence the genome by hybridisation was also attracting interest.

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11. As I remember the conference, I gave a brief overview of the programs underway at Affymax at the time and some of the approaches that we were considering. As I mentioned above, the most well known example of the Affymax technology appeared in *Science* in February 1991. Figure 8 showed the result of an experiment which applied photolithography in the synthesis of a checkerboard pattern of nucleotides. It is likely that I used the figure from the *Science* paper (or one very similar) as a reference point in part of my talk, as the paper as a whole was well known at that time; I imagine that the dimers referred to by Dr. Silverman refer to those shown in such a figure. The illustration and the procedure to create it were intended to show the applicability of our technique to the spatial localisation of nucleotides; they did not seek to demonstrate anything about the length of nucleotide that could or could not be synthesised. To the contrary, the paper as a whole suggested broad applicability of the technique.

12. I cannot remember the specific details of the content of my presentation, but there was considerable interest in our technique to generate high density arrays of polynucleotides. I most likely would have included the general approach of the technology we were developing and some of the implications of that approach. I would expect there to have been a discussion section as mentioned in Dr. Silverman's note, but I do not recall details of the exact format of the discussions. Clearly, there was no inference, however, that the technique was limited.

13. I certainly did not believe in 1991 that dimer or trimer formation represented the longest length of nucleotide that we could produce and I am still of that opinion. On the contrary, I was committed to the commercial optimisation of the technique that has become the gold standard in the industry. Moreover, I also believed in 1991 that it would be a simple matter to create a nucleotide array of longer than 3 bases using photolithographic techniques to spatially define the regions of the

array. Therefore, I cannot imagine that I gave the impression that there were significant technical difficulties in creating such an array.

14. I certainly would not have told the audience about all of the research work that was being done at Affymax on nucleic acid arrays as, for the reasons outlined above, much of it was directed at commercial goals that would be maintained in secret. Our goal was to produce commercially available polynucleotide arrays, and we were not at that stage of production at that time. However, I had no doubt that in November 1991 that we could synthesise in spatially localised areas oligonucleotides of virtually any length that would be supported by standard solid phase chemistry with the methods that we had developed with photochemical addressability.

And I make this solemn declaration sincerely believing the same to be true.

Dated this 12th day of October 2000

Signed .....

DR. STEPHEN P.A. FODOR

EXHIBIT U

Doc. 41

27.12.00

D62

IN THE MATTER OF
European Patent No. 0 619 321
of Affymetrix Inc. and
Oppositions thereto

DECLARATION OF J. LEIGHTON READ, M.D.

I, J. LEIGHTON READ, M.D., do hereby solemnly and sincerely declare as follows:

1. I am the founder and Chairman of Aviron, a biopharmaceutical company. I am one of the co-inventors of EP 0 619 321 (the "Patent").

2. I have read the declaration of Dr. Michael Pirrung filed by Incyte Pharmaceuticals, an Opponent of the Patent and I make this declaration to comment principally on Dr. Pirrung's relationship with Affymetrix and Dr. Fodor, now the Chairman of Affymetrix.

3. I helped found and set up Affymax N.V. and its subsidiary companies in 1988 and 1989 under the direction of Dr. Alejandro Zaffaroni. I was a managing director of the parent company and the Chief Operating Officer of Affymax from its inception through late 1989 and President of the Pharma Division until July, 1989. I had a good knowledge of the people involved with Affymax, including Dr. Pirrung, while I was organizing Affymax and as an officer of the company during that period. I worked with Dr. Pirrung from the time he joined us in late 1988 until he left Affymax in late 1989.

4. Dr. Pirrung was introduced to us by one of the Affymax scientific advisors who was a Stanford faculty member. When I interviewed Dr. Pirrung, he explained that he had been denied tenure for a permanent position in the Chemistry Department at Stanford and would be interested in working for Affymax half time

to see if he liked working in industry, while he also looked for faculty positions elsewhere. The references I checked reported that Dr. Pirrung was very bright but had difficulty getting along with some of the faculty members in his department and some of his own graduate students. We were impressed with his credentials and after a brief time offered him a half-time position as a scientist in the company. Throughout his early employment by Affymax, he maintained an office at Stanford where he spent much of his time, participating in specific meetings at Affymax when requested and contributing ideas and comments at the scientific review meetings.

5. Dr. Pirrung was enthusiastic about using the technology to build arrays of oligopeptides and oligonucleotides and offered many suggestions regarding photochemistry, coupling chemistry and specific building blocks. On several occasions I encouraged Dr. Pirrung to set up a lab at Affymax to pursue experiments, buy equipment and hire personnel, but, he did not move forward as requested.

6. He also had difficulty in influencing the work in the organic chemistry laboratory of Dr. Ron Hale, whose group at Affymax was actively conducting experiments at that time. I had to ask him to develop a more productive working relationship with Dr. Hale's group on several occasions. I was disappointed with how little Dr. Pirrung was contributing to our progress despite our encouragement.

7. In early 1989, Dr. Zaffaroni and I recruited Dr. Lubert Stryer to become President of Affymax Research Institute and our chief scientist. I believe that our array technology was one of the key opportunities that enabled us to attract such a distinguished Stanford faculty member to the company. One of Dr. Stryer's first priorities was to get additional effort underway at Affymax on our array technology. With Dr. Stryer's assistance, we recruited Dr. Stephen Fodor from the University of California at Berkeley. It was immediately apparent to us that

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Dr. Fodor was able to get things done. Indeed, within a few days of his joining Affymax he had asked me to approve the purchase of optics equipment costing over $100,000, which I authorised. Dr. Fodor made rapid progress. He established a laboratory, hired people to help him and started experiments. Dr. Fodor took the ball and ran with it. This was the beginning, I believe, of Dr. Pirrung's apparent disaffection of Dr. Fodor. Dr. Pirrung complained that he was not being listened to, that he was not appreciated and that he was not getting his full recognition.

8. By late 1989 Dr. Pirrung was seemingly getting increasingly frustrated at the success of Dr. Fodor and his work, and also his disagreements with others in the company. Although Dr. Pirrung was, by then, not on good terms with some of the senior scientists at Affymax, we nevertheless offered him various titles and positions that would not have required him to work directly with Dr. Fodor. However, he chose to leave to take up a full-time position at Duke University, although he remained a consultant to Affymax for a number of years.

9. Another disagreement between Dr. Pirrung and Dr. Fodor that I am aware of occurred after Dr. Pirrung had left Affymax. This concerned the primary authorship of a paper I co-authored that was published in the journal "Science" in 1991. This is a highly prestigious journal and Dr. Pirrung wanted to be the primary author. I also understand that there were differences between them in the content of the paper.

10. After Dr. Pirrung left Affymax, I believe from my interactions with him that Dr. Pirrung was upset about the way Dr. Fodor was leading and directing the array program at Affymax and subsequently Affymetrix (when Affymetrix was set up as a separate company by Affymax). Although Dr. Pirrung was apparently trying to stake a claim in the field after leaving Affymax, it was Dr. Fodor who received the greatest public attention.

11. Finally, I am not aware that Dr. Pirrung had any direct participation in experimental work relating to DNA arrays much after the first US priority patent application filing in June 1989, at Affymax. I also have no reason to believe that Dr. Pirrung was aware of the details of experimental work on DNA arrays, and in particular the results being obtained, after he left Affymax. It is not at all clear to me, therefore, that Dr. Pirrung would have any first-hand knowledge of the detail of the results or conclusions being drawn from research at Affymax in 1990 as he purports to discuss in his declaration.

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And I make this solemn declaration sincerely believing the same to be true.

Dated this 30th day of October 2000

Signed .....

DR. J. LEIGHTON READ

EXHIBIT V

D63

Dep. 21

N 08.04.02

IN THE MATTER OF
European Patent No. 0 619 321
of Affymetrix Inc. and
Oppositions thereto

DECLARATION OF PROFESSOR LUBERT STRYER, M.D.

I, LUBERT STRYER M.D., do hereby solemnly and sincerely declare as follows:

1. I am Winzer Professor in the School of Medicine and Professor of Neurobiology at Stanford University, and am a member of the National Academy of Sciences. I am co-inventor of EP 0 619 321 (the "Patent"). I currently serve as Chairman of the Scientific Advisory Board of Affymetrix, Inc. ("Affymetrix"). A copy of my Curriculum Vitae and list of publications and patents is attached.

2. I have read a redacted version of the declaration of Dr Michael Pirrung filed by an Opponent of the Patent, and I have been asked by Affymetrix to comment on Dr Pirrung's relationship with Affymetrix.

3. I was a Scientific Advisor to Affymax (Affymax NV, the company from which Affymetrix split off as a separate corporation in 1993) from February 1989 to September 1989, when I became President and Scientific Director of the Affymax Research Institute, a subsidiary of Affymax. In September 1990, I left Affymax and returned to Stanford University, and in October 1991, I resumed my relationship with Affymax as a Scientific Advisor.

4. I worked with Dr Pirrung in 1989, and also with Drs Stephen Fodor and Leighton Read in 1989 and 1990, while I was at Affymax, on the invention and development of the technology described in the Patent.

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5. To the best of my recollection, Dr Pirrung left Affymax during that time, towards the end of 1989, to take an academic position at Duke University. It is my recollection that Dr Pirrung was not directly involved in any experimental work on the synthesis of DNA arrays at Affymax or Affymetrix while I was associated with either company, i.e. during the period February 1989 to August 1990, and after October 1991.

6. I was aware as early as 1990 that the professional relationship between Dr. Fodor and Dr. Pirrung was strained.

7. Dr. Fodor and I wrote essentially the entire contents of the article entitled "Light-activated, Spatially Addressable Parallel Chemical Synthesis", which was published in *Science*, while I served as Scientific Director of the Affymax Research Institute. One of my responsibilities as Scientific Director was to decide on the list and order of authors of Affymax scientific papers. It was clear to me from the outset of the writing that Dr. Fodor would be first author of the *Science* article because Dr. Fodor directed this research program and had carried out most of the key experiments reported in the article. It is my recollection that Dr. Pirrung carried out none of the experiments described in the paper and did not participate in the writing of the manuscript.

And I make this solemn declaration sincerely believing the same to be true.

Dated this 6th day of March 2002.

Signed .....

DR. LUBERT STRYER

EXHIBIT W

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Briefs and Other Related Documents

Only the Westlaw citation is currently available.This case was not selected for publication in the Federal Reporter.NOTE: Pursuant to Fed.Cir.R. 47.6, this order is not citable as precedent. It is public record. Please use FIND to look at the applicable circuit court rule before citing this opinion. Federal Circuit Rule 47.6. (FIND CTAF Rule 47.6.)

United States Court of Appeals,Federal Circuit.

AVENTIS PHARMA S.A. and Aventis Pharmaceuticals Inc., Plaintiffs-Appellants,

v.

AMPHASTAR PHARMACEUTICALS, INC., Defendant-Appellee,

andTeva Pharmaceuticals USA, Inc., Defendant-Appellee.

No. 05-1513.

April 10, 2006.

Rehearing and Rehearing En Banc Denied June 7, 2006.

Background: Pharmaceutical company brought action alleging infringement of patent directed to low molecular weight heparins (LMWHs) used to inhibit blood clots. The United States District Court for the Central District of California, 390 F.Supp.2d 936, granted defendants' motion for summary judgment on its affirmative defense and counterclaim of inequitable conduct, and, 390 F.Supp.2d 952, granted company's motion to substitute reissue patent for patent originally identified in its complaint. Company appealed summary judgment.

Holdings: The Court of Appeals, Prost, Circuit Judge, held that:

1(1) company's withholding of dosage information was a failure to disclose material information to the Patent and Trademark Office (PTO), and

2(2) genuine issues of material fact as to whether comparisons made by company in its patent application were made with an intent to deceive precluded summary judgment.

Reversed and remanded.

[1] Patents 291 97

291 Patents
291IV Applications and Proceedings Thereon
291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

Pharmaceutical company's withholding of dosage information for claimed invention, which was directed to low molecular weight heparins (LMWHs) used to inhibit blood clots, prevented Patent and Trademark Office's (PTO) examiner from considering material information in deciding whether to allow application and was therefore a failure to disclose material information to the PTO.

[2] Patents 291 323.2(3)

291 Patents
291XII Infringement
291XII(C) Suits in Equity
291k323 Final Judgment or Decree
291k323.2 Summary Judgment
291k323.2(3) k. Particular Cases. Most Cited Cases

Genuine issues of material fact as to whether comparisons made by pharmaceutical company in its patent application for claimed invention, which was directed to low molecular weight heparins (LMWHs) used to inhibit blood clots, were made with an intent to deceive precluded summary judgment in infringement action.

Patents 291 328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original Utility. Most Cited Cases

Patents 291 328(4)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(4) k. Reissue. Most Cited Cases

5,389,618. Cited.

38,743. Cited.

Before RADER, SCHALL, and PROST, Circuit Judges.

PROST, Circuit Judge.

*1 Aventis Pharma S.A. and Aventis Pharmaceuticals, Inc., (collectively, "Aventis") appeal from decisions of the United States District Court for the Central District of California granting summary judgment in favor of Amphastar Pharmaceuticals, Inc., ("Amphastar") and Teva Pharmaceuticals USA, Inc., ("Teva") (jointly "appellees") holding unenforceable United States Patent No. 5,389,618 ("the '618 patent"), *Aventis Pharma S.A. v. Amphastar Pharm.*, 390 F.Supp.2d 936 (C.D.Cal.2005) (*"Aventis Opinion"*), and United States Reissue Patent No. 38,743 ("the '743 reissue patent"), *Aventis Pharma S.A. v. Amphastar Pharm.*, 390 F.Supp.2d 952 (C.D.Cal.2005). Although there are no genuine issues of material fact with respect to materiality, because genuine issues of material fact remain as to intent, we *reverse* the district court's grant of summary judgment of inequitable conduct and *remand* for further proceedings consistent with this opinion.

BACKGROUND

The '618 patent and the '743 reissue patent disclose and claim mixtures of low molecular weight herapin ("LMWH") used to prevent blood clots. During prosecution of the application leading to the '618 patent and the '743 reissue patent, Aventis compared the half-life of a product allegedly covered by the '618 patent (Example 6 of the '618 patent or "Debrie LMWH") at a 40 mg dose to the half-life of a prior art product ("EP 40,144 LMWH" or "Mardiguian LMWH") at a 60 mg dose. Aventis made these comparisons to the Patent and Trademark Office ("PTO") in the patent application, in several office action responses, and in two declarations by a French scientist named Dr. Andre Uzan to show an unexpected and significantly better half-life of Debrie LMWH when compared to EP 40,144 LMWH. Aventis did not, however, expressly disclose the dosages at which the half-life comparisons were made, and specifically, that the EP 40,144 LMWH data was for a 60 mg dose.

The '618 patent and the '743 reissue patent purportedly cover drug compositions called Lovenox® that are approved by the Food and Drug Administration ("FDA"). Amphastar and Teva filed Abbreviated New Drug Applications ("ANDAs") with the FDA to obtain approval to market generic versions of Lovenox® . In response, Aventis, the owners of the '618 patent and the '743 reissue patent, filed a patent infringement suit against Amphastar and Teva in the United States District Court for the Central District of California.

The district court granted a motion for summary judgment of unenforceability due to inequitable conduct submitted by Amphastar. Without holding a hearing, the court concluded that Aventis's repeated representations of patentability based on the purported improved half-life of Debrie LMWH were material. The court faulted Aventis for comparing data based on different doses to show an improved half-life, when a comparison of available data using the same doses actually showed that there was little if any difference between the half-lives of the prior art and the purported invention. The court rejected Aventis's argument that Dr. Uzan's first declaration can reasonably be interpreted as meaning that the disclosed half-life data was based on different dosages, calling the argument "specious."

***2** Regarding intent, the court rejected Aventis's argument that the use of the 40 mg Debrie LMWH data, as opposed to the 60 mg Debrie LMWH data, was reasonable. The court stated that the question is not whether use of the 40 mg data was reasonable, but whether there was an omission of material fact, particularly in light of the fact that the same study showed that the 60 mg Debrie LMWH data and the 60 mg EP 40,144 LMWH data was much closer than the 40 mg Debrie LMWH data and the 60 mg EP 40,144 LMWH data. Based on these circumstances, the court found that the facts support a strong inference of intent. The court then weighed materiality and intent. It found weighty uncontroverted evidence sufficient to establish materiality and intent to deceive, and further stated that Aventis submitted just a scintilla of evidence in opposition. It therefore granted summary judgment of unenforceability due to inequitable conduct.[FN1]

Aventis timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

A. Standards of Review

We review a district court's grant of summary

judgment under the law of the applicable regional circuit. *CollegeNet Inc. v. ApplyYourself Inc.*, 418 F.3d 1225, 1230 (Fed.Cir.2005). In the Ninth Circuit, a grant of summary judgment is reviewed de novo. *Leonel v. Am. Airlines, Inc.*, 400 F.3d 702, 708 (9th Cir.2005). "We must determine 'whether, viewing the evidence in the light most favorable to the nonmoving party, there are any genuine issues of material fact and whether the district court correctly applied the relevant substantive law." ' *Id.* (quoting *Lopez v. Smith*, 203 F.3d 1122, 1131 (9th Cir.2000) (en banc)).

This court recently stated the standards for finding inequitable conduct as follows:
Applicants for patents have a duty to prosecute patents in the PTO with candor and good faith, including a duty to disclose information known to the applicants to be material to patentability. A breach of this duty may constitute inequitable conduct, which can arise from an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive or mislead the PTO. A party asserting that a patent is unenforceable due to inequitable conduct must prove materiality and intent by clear and convincing evidence. Once threshold findings of materiality and intent are established, the trial court must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred. This requires a careful balancing: when the misrepresentation or withheld information is highly material, a lesser quantum of proof is needed to establish the requisite intent. In contrast, the less material the information, the greater the proof must be.

Purdue Pharma L.P. v. Endo Pharm., Inc., 438 F.3d 1123, 1128-29 (Fed.Cir.2006) (citations omitted).

B. Materiality

[1] We first consider whether there is any issue of material fact that the applicant for the '618 patent failed to disclose material facts to the PTO. The threshold showing of materiality required to proceed to the "balancing" portion of the inequitable conduct inquiry can be met by showing a reasonable examiner would have considered such information important in deciding whether to allow the application. *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1316 (Fed.Cir.2006).

***3** The district court first determined that "Amphastar, by clear and convincing evidence, has met its initial burden of identifying for the court those portions of the materials on file that it believes demonstrates the absence of any genuine issue of material fact with respect to Aventis's failure to disclose material information." *Aventis Opinion*, 390 F.Supp.2d at 946. We agree that based on Aventis's undisputed omissions, Amphastar met its initial burden of showing that Aventis failed to disclose material information. Aventis never disclosed during prosecution that it derived the half-life data for the EP 40,144 LMWH at a 60 mg dose. The half-life comparisons were highly material to patentability. In multiple office actions, the examiner rejected claims for the Debrie compounds based on the EP 40,144 patent. Each time, Aventis distinguished the Debrie compounds based on their "significant" increase in half-life over the EP 40,144 compounds without providing any information regarding the dosage at which the data for either compound was obtained. In its final office action, Aventis provided three tables of test data: 1) Debrie LMWHs labeled as obtained at 40 mg; 2) Debrie LMWH labeled as obtained at 60 mg; and 3) EP 40,144 LMWH without a label as to its dosage. The failure to disclose that the EP 40,144 data was obtained at 60 mg denied the examiner an opportunity to determine whether the differences in half-lives between the Debrie and EP 40,144 compounds were significant. Therefore, an omission that would have revealed that the difference in half-lives was actually much smaller was material to patentability. A comparison made at the same dosage, 60 mg, would have yielded a much smaller difference in half-life. Given the centrality of the differences in half-lives to patentability, by failing to disclose the dosage of the 60 mg compound or to disclose that the difference in half-lives at the same dosage was actually lower, Aventis failed to disclose material information to the PTO.

The district court then found that Aventis failed to establish any facts showing a genuine issue of material fact that a material omission was made in prosecution of the '618 patent. *Id.* at 946.

On appeal, Aventis argues that it has raised material facts regarding materiality of the omission. Aventis contends that if the dose information was material, the examiner would have requested it because 1) she was presented with half-life data that enabled her to compare various doses, and 2) she had a motivation to compare them. Aventis argues that the examiner would have been so motivated because Dr. Uzan did inform the examiner that the dosage comparison was done at different dosages, Dr. Uzan never expressly

represented that he was comparing half-life at the same dose, those of skill in the art frequently compared half-lives at different doses and so the examiner should have assumed this here, and because the specification teaches that the half-life of the claimed products are independent of dose. We reject these arguments.

***4** In support of its argument that Dr. Uzan did inform the examiner that the dosage comparison was done at different dosages, Aventis points to language in Dr. Uzan's March 29, 1993 declaration, stating:
the claimed formulations had a plasma half life longer than 4 1/2 hours in 45% of the cases in contrast to Mardiguan [sic] who achieved such a half life in only 17% of the cases. This represents an increase in 250% in the half life and is very significant because *it enables the same effect to be achieved with lower dosages.*

(J.A. 1894) (emphasis added). Dr. Uzan explained at his deposition that he believes that the second sentence "say[s] that the comparison is a comparison between two doses of which one is lower than the other." (J.A. 2119-20.) Aventis's rebuttal expert claimed the statement "reasonably conveys that at a lower dose of the [Debrie] product, a higher percentage of subjects exhibited a half-life longer than 4 1/2 hours." (J.A. 1010.) Aventis maintains that the court erred in dismissing this interpretation of the sentence as "specious," and argues that, at a minimum, the testimony is subject to reasonable debate.

Although Dr. Uzan may have had some doubt as to the meaning of his statement, we find there is no reasonable debate as to what it stated to the patent office. A reasonable examiner would understand the statement only to allege a benefit of the claimed invention, not as a disclosure that different dosages were being compared. Aventis's own statements incorporating Dr. Uzan's declaration support this conclusion. For example, in one office action, Aventis stated:
[T]he half life obtained for the claimed preparation was 4.36 +1.07 hours whereas that for Mardiguian was 3.33 +0.2 hours. This is approximately a 30% difference in results and is significant in that it means that *the claimed preparations can be administered in significantly lower doses.*

(J.A.1933) (emphasis added); (*see also* J.A. 1885-86 (referencing Dr. Uzan's statement)). It is not plausible to read these statements as indicating to the examiner that the data for the Debrie LMWH was obtained for a lower dose than the Mardiguian LMWH. They tell the examiner that the longer half-life of the claimed invention is a benefit. We therefore agree with the district court that there is no genuine issue of material fact that Dr. Uzan did not disclose in this statement that the comparison was made using data from different doses. [FN2]

Second, although Aventis did not expressly represent that the half-life comparison was at the same dosage, it repeatedly compared the 40 mg Debrie LMWH table's data with the unlabelled EP 40,144 data. By making the comparison at different dosages without disclosing that this was so, Aventis led the examiner away from any questions about dosage or any motivation to question the dosage for the EP 40,144 data.

In addition, we reject Aventis's argument that the examiner would be motivated to compare half-lives at different dosages, as this was common practice. In each of the prior art references Aventis cites as showing comparisons at different dosages, the differences in dosages was expressly disclosed. In addition, although a comparison of preferred therapeutic doses may be the norm, there is no evidence that the examiner was ever made aware that the preferred therapeutic dose for the Debrie compound was 40 mg. Therefore, though it may at times be reasonable to compare half-lives for different dosages would not have motivated the examiner to compare the unlabelled 60 mg EP 40,144 data with the 60 mg Debrie data, when the comparison provided used the 40 mg Debrie data.

***5** Finally, we reject Aventis's position that the examiner would be motivated to compare different dosages because the specification stated that the claimed compounds were dose independent. Indeed, if the examiner truly credited the fact that the Debrie LMWHs are dose independent, the examiner would have had no reason to compare the EP 40,144 data with different doses of the Debrie data because the Debrie data at different doses would be the same. In addition, the examiner could not have been aware of whether the EP 40,144 data was for a particular dose or for some combination of dosages, such that a comparison would be irrelevant.

In summary, it was insufficient to merely submit the underlying data to the examiner and later argue that the examiner could have requested the EP 40,144 dosage information to make additional comparisons. The withholding of the EP 40,144 dosage information prevented the examiner from considering

information important in deciding whether to allow the application, and was therefore a failure to disclose material information to the PTO. *Digital Control*, 437 F.3d at 1314.

C. Intent to Deceive the PTO

[2] Even if an omission is found to be material, the omission must also be found to have been made with the intent to deceive. "Materiality does not presume intent, which is a separate and essential component of inequitable conduct." *GFI, Inc. v. Franklin, Corp.*, 265 F.3d 1268, 1274 (Fed.Cir.2001) (quoting *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 552 (Fed.Cir.1990)). To find an intent to deceive, "the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1189 (Fed.Cir.1993) (quoting *Kingsdown Med. Consultants Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed.Cir.1988) (en banc)). "Intent need not be shown by direct evidence, but may be inferred from the totality of the evidence." *Digital Control*, 437 F.3d at 1319. However, "[i]n the summary judgment context, all inferences must be made in favor of the nonmovant; thus, it is often improper to determine at summary judgment that a patentee made intentional misstatements or omissions to the PTO." *Id.* at 1317. On summary judgment, to create a genuine issue of material fact, Aventis was required to state specific facts supporting a plausible justification or excuse for its failure to disclose material information. *Paragon Podiatry*, 984 F.2d at 1191.

Here, the district court did not find direct evidence of intent to deceive, but found that the "facts and circumstances surrounding the failure to disclose the dose differential ... supports a strong inference of intent by Aventis to deceive the PTO." *Aventis Opinion*, 390 F.Supp.2d at 951-52. Aventis contends that the district court erred in finding an intent to deceive on summary judgment by denying Dr. Uzan an opportunity to testify in person, ignoring evidence negating intent, misconstruing deposition testimony, and drawing factual inferences adverse to Aventis. Because Aventis has met its burden of setting forth a plausible justification for its failure to disclose material information, deciding all inferences in favor of Aventis, we hold that the district court erred in finding intent to deceive on summary judgment.

*6 For example, the district court found it irrelevant whether comparison at different doses was reasonable. *Id.* at 951. On appeal, Teva also advocates this position, arguing that the relevant inquiry is whether there was an intent to deceive in failing to disclose the 60 mg dosage amount of the prior art product. We disagree. The reasonableness of the comparison between different dosages *is* relevant to determining whether the failure to disclose that the comparison was made using 60 mg EP 40,144 data was made with an intent to deceive. Because there exist genuine issues of material fact as to the reasonableness of the comparisons made by Aventis,[FN3] we must draw an inference for purposes of summary judgment that it was reasonable to compare the 40 mg Debrie half-life with the 60 mg EP 40,144 half-life. Accepting that inference, the district court was required to determine whether Aventis still intended to deceive by withholding the dosages at which the comparisons were made.

Aventis maintains that Dr. Uzan had a reasonable belief that he informed the examiner that his half-life comparison was made at different doses and that he could not have intended to deceive because he disclosed the data based on 60 mg. Aventis further explains that Dr. Uzan had no reason to make a prospective statement about what would be possible using a lower dose based on a comparison at the same dose, because he could and did directly make that point by comparing the 60 mg EP 40,144 LMWH data against the 40 mg Debrie LMWH data. Aventis also points out that the district court did not even reference, let alone draw reasonable inferences from the fact that Dr. Uzan submitted the half-life data for 60 mg of Debrie LMWH, which would allow the examiner to compare the data from equal doses.

Although the district court did not reference all of Aventis's arguments, it ultimately concluded that the facts supported a strong inference of intent to deceive. The district court's inference was reasonable-by failing to disclose that the EP 40,144 data was at a 60 mg dose, Aventis may have been painting the rosiest picture possible as to the half-life improvement of its claimed compounds in an attempt to deceive the examiner.[FN4] Appellees contend that this is only reasonable inference to draw from the facts presented.

However, there is another reasonable inference-namely, as Aventis argues, if the comparison between different doses was reasonable, the failure to disclose may have been due purely to inadvertence. Based on the facts presented by Aventis, these are not "insupportable, [or] specious ... explanations or

excuses." *Paragon Podiatry*, 984 F.2d at 1190. Neither are Aventis's contentions merely "[c]onclusory allegations and attorney arguments." *Ferring v. Barr*, 437 F.3d 1181, 1193 (Fed.Cir.2006). Aventis presents declarations from the inventor, the declarant, and an expert witness stating facts supporting a "plausible justification" for its material omission. *Paragon Podiatry*, 984 F.2d at 1191. Therefore, a finding of intent was inappropriate on summary judgment.

CONCLUSION

*7 While we agree with the district court with regard to its finding of materiality on summary judgment, there remain genuine issues of material fact regarding Aventis's intent to deceive the PTO. Therefore, we reverse the district court's decisions granting summary judgment of unenforceability of the '618 patent and '743 reissue patent and remand for further proceedings consistent with this opinion.

FN1. Aventis filed the reissue application that led to the '743 reissue patent before filing suit against Amphastar and Teva. During prosecution of the reissue application, Aventis informed the examiner that it was not relying on any statement or argument based on Example 6 made during prosecution of the application leading to the '618 patent. The '743 reissue patent issued, and therefore Aventis surrendered the '618 patent by operation of law, the day before the district court granted Amphastar's summary judgment motion with respect to the '618 patent. After granting summary judgment on the '618 patent, the court applied the holding of *Hoffman-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684, 688-89 (Fed.Cir.1990) (inequitable conduct in original patent renders any reissue patent unenforceable), to enter summary judgment of unenforceability against the '743 reissue patent. *Aventis Pharma*, 390 F.Supp.2d at 954-55.

FN2. If, as Aventis argues, Dr. Uzan did actually believe he was disclosing a comparison of different doses, in part because he is a native French speaker, this may go to his intent, as discussed further below.

FN3. For example, Aventis argues the comparison was reasonable because: 1) it reflects the preferred dosage level for therapeutic reasons; 2) the 60 mg dosage level was not preferred because it caused bleeding in some patients; and 3) the 40 mg dosage level was more reliable because it had been confirmed in a separate study.

FN4. Even the disclosure of the 60 mg Debrie data might ultimately militate a finding of intent to deceive because it implies that Dr. Uzan was aware that the 60 mg data was relevant to the comparison, but did not specifically tell the examiner why.

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Briefs and Other Related Documents (Back to top)

- 2005 WL 3445884 (Appellate Brief) Non-Confidential Reply Brief of Plaintiffs-Appellants Aventis Pharma S.A. and Aventis Pharmaceuticals Inc. (Nov. 7, 2005) Original Image of this Document (PDF)
- 2005 WL 3445883 (Appellate Brief) Corrected Non-Confidential Brief for Defendant-Appellee Amphastar Pharmaceuticals, Inc. (Oct. 24, 2005) Original Image of this Document with Appendix (PDF)
- 2005 WL 3445886 (Appellate Brief) Non-Confidential Brief for the Defendant-Appellee Teva Pharmaceuticals USA, Inc. (Oct. 24, 2005) Original Image of this Document (PDF)
- 2005 WL 3517956 (Appellate Brief) Non-Confidential Brief for the Defendant-Appellee Teva Pharmaceuticals USA, Inc. (Oct. 24, 2005) Original Image of this Document (PDF)
- 2005 WL 2802523 (Appellate Brief) Non-Confidential Brief of Plaintiffs-Appellants Aventis Pharma S.A. and Aventis Pharmaceuticals Inc. (Sep. 12, 2005) Original Image of this Document with Appendix (PDF)
- 05-1513 (Docket) (Aug. 11, 2005)

END OF DOCUMENT

EXHIBIT X

Westlaw.
Not Reported in F.Supp.2d
Not Reported in F.Supp.2d, 2005 WL 588341 (N.D.Cal.)
(Cite as: Not Reported in F.Supp.2d)

H

Briefs and Other Related Documents

Only the Westlaw citation is currently available.

United States District Court,N.D. California.

ICU MEDICAL, INC., Plaintiff,

v.

B.BRAUN MEDICAL INC., Defendants.

No. C 01-3202 CRB.

March 14, 2005.

Christopher B. Hockett, Bingham McCutchen LLP, San Francisco, CA, Mary T. Huser, Thomas E. Kuhnle, Adrienne L. Taclas, Mary A. Fuller, Susan Vastano Vaughan, Bingham McCutchen LLP, East Palo Alto, CA, S. Christian Platt, Paul, Hastings, Janofsky & Walker LLP, San Diego, CA, for Plaintiff.

Tony L. Richardson, Kirkland & Ellis, Los Angeles, CA, Daniel F. Attridge, Edward C. Donovan, Gregory Corbett, John Thomas Battaglia, Justin P.D. Wilcox, Kirkland & Ellis LLP, Washington, DC, for Defendants.

ORDER RE: MOTIONS FOR SUMMARY JUDGMENT AND SCHEDULING TRIAL

BREYER, J.

*1 Plaintiff and Counterclaim Defendant ICU Medical, Inc. ("ICU") brought this suit against Defendant and Counterclaimant B.Braun Medical, Inc. ("Braun") for infringement of U.S. Patent No. 5,928,204 ("the '204 patent") and U.S. Patent No. 6,669,673 ("the '673 patent") by manufacturing and selling a specialized needleless medical connector. The patents relate to a medical valve for use in controlling the flow of fluid between two medical implements. The alleged infringing device is Braun's Ultrasite valve.

ICU and Braun cross-move for summary judgment on the issue of whether the Ultrasite valve [FN1] infringes the '673 patent. Braun also seeks summary judgment of non-infringement of both the '673 and '204 patents by the Ultrasite valve with modified piston. Finally, ICU moves for summary judgment that the '673 patent is not unenforceable due to inequitable conduct on the part of the patentee.

FN1. In late 2004, Braun made a modification to the Ultrasite valve by changing the molds used in manufacturing the piston component to remove an alleged "taper" in the piston skirt. The modified valve will be referred to in this Order as the Ultrasite valve with modified piston. Otherwise, the term "Ultrasite valve" will refer to both the unmodified Ultrasite valve and the Ultrasite valve with modified piston.

Having carefully considered the parties' papers, and with the benefit of oral argument on February 11, 2005, the Court hereby resolves the motions as follows:

1. ICU's motion for summary judgment that Braun's Ultrasite valve infringes the '673 patent is GRANTED in part as to claims 1-2 and 5-6, and DENIED in part as to claim 3.
2. Braun's motion for summary judgment that the Ultrasite valve does not infringe the '673 patent is DENIED in part as to claims 1-2 and 4-6, and GRANTED in part as to claim 3.
3. Braun's motion for summary judgment that the Ultrasite valve with modified piston does not infringe the '673 and '204 patents is GRANTED.
4. ICU's motion for summary judgment of no inequitable conduct is DENIED.

BACKGROUND

The administration of medication in hospital and medical settings routinely involves the use of connectors and adaptors for facilitating the movement of fluids (e.g., drugs and intravenous solutions) between medical implements. Since the ready passage of fluids through the connectors and adaptors is often critical to patient survival, it is important that they operate reliably and repeatedly. Both Braun and ICU are providers of needleless medical connectors.

Braun's Ultrasite valve is a needle-free, capless, swabbable valve. It contains a piston made of flexible material. When the piston is in its uncompressed state, it seals against the housing of the valve preventing fluid flow through the valve. In this state, the wall of the piston is relatively flat. When a syringe or other appropriate medical device is connected to the valve, the piston is compressed

causing the piston wall to buckle. The compressed piston no longer completely seals against the valve housing because the portion of the piston that seals against the housing is moved to a location where there are channels in the housing. When the piston is compressed, fluid can flow through the valve.

ICU is the assignee of two patents (the '673 and '204 patents) for a closed system, needleless valve device which automatically reseals after administering medication using a medical implement that directly connects with the system without the need of any intermediary needles, caps, or adaptors.

I. THE '673 PATENT

***2** Independent claim 1 reads:
A medical valve for controlling the flow of fluid between a first medical implement and a second medical implement, said valve comprising:
....
... a flexible element positioned in said cavity movable between an uncompressed position in which a portion of the flexible element bears against the wall structure near said opening and obstructs fluid flow through said valve and a compressed position in which fluid flow is permitted through said valve, said flexible element comprising a wall with an inner surface and an outer surface, the wall flexing to accommodate axial compression of said flexible element, said flexible element comprising an end fitting against a ring shaped support to assist in securing said flexible element in said cavity, said flexible element in said uncompressed position comprising a first external diameter near said opening, a second external diameter in said main portion, said second diameter being smaller than said first diameter and said third diameter, and at least a portion of the outer surface of the wall of the flexible element between the second diameter and the third diameter being tapered.

U.S. Patent No. 6,669,673 (issued Dec. 30, 2003). Claims 2-6 are dependent claims from claim 1.

The Court issued its claim construction order regarding the '673 patent on November 8, 2004 (the "Markman Order"). In its Markman Order, the Court determined that the term "flexible element" should be defined as "a portion of the valve that is capable of being bent, usually without breaking." Markman Order at 7. The flexible element must be moveable from an uncompressed position, in which the valve is closed, to a compressed position, in which "it is under axial compression from a medical implement" and "the valve is in an open state and fluid is allowed to move through it." *Id.* at 9, 7. When the flexible element is in an uncompressed position, it must "bear against the wall structure" and "obstruct[ ] fluid flow" through the valve. '673 Patent Claim 1.

II. THE '204 PATENT

Independent claim 1 reads:
A seal for use in selectively opening and closing a fluid pathway through a medical connector comprising a resilient seal element having a wall having a top end and a bottom end, said wall including at least two generally arcuate segments each having an outwardly extending portion, said segments intersecting one another and defining at least one space between where said segments intersect and a line tangential to the outwardly extending portions of both segments, and at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element.

U.S. Patent No. 5,928,204 (issued July 27, 1999). Claims 2-5 are dependent claims from claim 1.

DISCUSSION

ICU and Braun cross-move for summary judgment on the issue of whether Braun's Ultrasite valve infringes claims 1-3 and 5-6 of the '673 patent. Braun also seeks summary judgment of non-infringement by the Ultrasite valve with modified piston with regard to claims 1-6 of the '673 patent and claims 1-5 of the '204 patent. Finally, ICU moves for summary judgment that the '673 patent is not unenforceable due to inequitable conduct on the part of the patentee.

I. STANDARD OF REVIEW FOR SUMMARY JUDGMENT

***3** Summary judgment is appropriate when the "pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). An issue is "genuine" only if there is sufficient evidence for a reasonable fact finder to find for the non-moving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49, 106 S.Ct. 2505, 91 L.Ed.2d

202 (1986). A fact is "material" if the fact may affect the outcome of the case. *See id.* at 248. "In considering a motion for summary judgment, the court may not weigh the evidence or make credibility determinations, and is required to draw all inferences in a light most favorable to the non-moving party." *Freeman v. Arpaio*, 125 F.3d 732, 735 (9th Cir.1997). A principal purpose of the summary judgment procedure is to identify and dispose of factually unsupported claims. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

The party moving for summary judgment bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *See id.* at 323. Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *See id.* Once the moving party meets this initial burden, the non-moving party must go beyond the pleadings and by its own evidence "set forth specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e). The non-moving party must "identify with reasonable particularity the evidence that precludes summary judgment." *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir.1996) (quoting *Richards v. Combined Ins. Co.*, 55 F.3d 247, 251 (7th Cir.1995), and noting that it is not a district court's task "to scour the record in search of a genuine issue of triable fact"). If the non-moving party fails to make this showing, the moving party is entitled to judgment as a matter of law. *See Celotex*, 477 U.S. at 323.

II. INFRINGEMENT OF THE '673 PATENT

A patent infringement analysis involves two steps: claim construction and then applying the construed claim to the accused device. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995). The first step, construing the claims to determine their meaning and scope, has been held to be purely a matter of law. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998). The second step, application of the claim to the accused device, is a fact-specific inquiry. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed.Cir.1998) ("[I]nfringement, whether literal or under the doctrine of equivalents, is a question of fact."). If each limitation of the patent claim is found in the accused device, either literally or as a substantial equivalent, the accused device infringes that claim. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).

***4** Summary judgment is appropriate in infringement suits when, drawing all reasonable inferences in favor of the non-moving party, there is no genuine issue of material fact. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed.Cir.1999). Because the relevant aspects of the accused device's structure and operation are undisputed in this case, the question of infringement collapses to one of claim construction and is particularly amenable to summary judgment. *Id.*

A. Literal Infringement

To establish literal infringement, the accused device must "contain each limitation of the claim exactly." *Litton Sys., Inc. v. Honeywell Inc.*, 140 F.3d 1449, 1454 (Fed.Cir.1998). The Court will proceed to compare the accused Ultrasite valve against all the claims and each of their limitations.

1. Claim 1 of the '673 patent

Claim 1 is the only independent claim of the '673 patent. It claims a medical valve for *controlling the flow of fluid* comprising a *flexible element* that: (1) *obstructs fluid flow* through the valve, (2) comprises *a wall flexing to accommodate axial compression* by a medical implement, (3) comprises *an end fitting against a ring shaped support,* and (4) is *tapered.* ICU asserts that Braun's Ultrasite valve satisfies each of these elements.

a. "Controlling the flow of fluid"

The Ultrasite valve plainly controls the flow of fluid from one medical implement to another. Braun's argument that its Ultrasite valve does not control fluid flow between two medical implements fails even under its own offered definition in which "control" means "to exercise restraint *or* direction over." Braun's Opposition Memorandum at 19 (quoting Random House Dictionary 442 (2d ed.1983)) (emphasis added). Removing the implement inserted into the top of the Ultrasite valve restrains the flow of fluid as the piston moves toward its uncompressed position. Inserting a medical implement opens the valve, allowing fluid to flow between that implement and another implement

connected to the other end of the valve. When the Ultrasite valve connects two medical implements, it controls the flow of fluid by restraining the fluid within the valve and directing the flow from one implement to the other.

The term "control" should not be read so narrowly as to require the regulation of any "maximum" or "minimum" fluid flow. The preferred embodiments in the '673 patent work in a similar way (as does the Ultrasite valve) to control the flow of fluid between two medical implements: inserting a syringe or other medical implement opens the valve by exposing passageways that allow fluid to flow from one implement to the other. The '673 patent does not recite a medical valve that independently starts, shuts off, slows-down, or speeds-up the flow of fluids. To accept Braun's argument would exclude the elected embodiments of the '673 prosecution, and produce a highly disfavored result for which Braun provides insufficient support. *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 362 F.3d 1367, 1381 (Fed.Cir.2004) (vacating summary judgment of non-infringement where accused infringer's claim interpretation would have excluded patent's preferred embodiment; such an interpretation is "rarely, if ever, correct.").

b. "Flexible element" that "obstructs fluid flow"

***5** Braun's Ultrasite valve also comprises a flexible element that obstructs fluid flow through the valve. In its claim construction, the Court construed the disputed claim language as follows. The term "flexible element" means "a portion of the valve that is capable of being bent, usually without breaking." Markman Order at 7. ICU does not assert that the entire piston assembly (including the piston component, rigid plug, and spring) constitutes the flexible element. Rather, ICU contends that only the piston component, or piston, infringes the "flexible element" limitation of claim 1.[FN2] ICU's Reply Memorandum at 4-5.

> FN2. For the purposes of this Order, the term "piston" refers to the piston component as opposed to the entire piston assembly.

The piston is clearly a flexible element under the claim language. It is made in a single molding of an elastomeric material, which allows it to flex or bend without breaking. The piston bends at several points during operation of the valve. In the uncompressed position, the lip of the piston flexes in response to radial pressure as it is squeezed into the neck of the housing. The shoulder of the piston flexes when it is pressed against the housing shoulder. The neck of the piston also flexes during insertion of the rigid plug and spring at assembly. The piston skirt flexes in response to axial pressure when it is moved into a compressed position by a medical implement.

Braun contends that the elastomeric piston is not "flexible" inside the valve because the rigid plug inserted into the neck of the piston is not flexible. The Court's construction, however, does not require that the flexible element must be bent, only that it is *capable* of being bent. Insertion of the rigid plug does not change the fact that the piston is still capable of being bent in response to pressure (e.g., radially from the rigid plug or housing wall, and axially from the medical implement), which is all the claim requires. Indeed, insertion of the rigid plug causes the piston neck to flex in response to radial pressure, and insertion of a medical implement causes the piston skirt to flex in response to axial pressure when it is moved into a compressed position.

Braun further contends that ICU's position is inconsistent with its earlier claim that the Ultrasite valve satisfies a "rigid sealing element" limitation in U.S. Patent No. 6,245,048 (the '048 patent). Claim 1 of the '048 patent recites "a rigid sealing element ... movable between a first position in which said seal prevents fluid flow and a second position in which fluid flow is permitted...." Braun's argument fails because ICU is not contending that the same features of the valve are both a "rigid sealing element" and a "flexible element." Rather, ICU refers to the stiffened lip and neck portion of the combined piston assembly as the "rigid sealing element," but only the piston component as the "flexible element." Although the Ultrasite piston assembly as a whole is rigid, the piston component remains flexible. It does not follow that a stiffened piston assembly cannot comprise a "flexible" piston which is capable of bending in response to pressure.

***6** The piston also obstructs fluid flow through the valve. In an uncompressed position, the lip of the piston bears against the housing wall and the rigid plug to create a seal that obstructs fluid from entering the valve. The piston shoulder also bears against the internal housing wall and prevents fluid from flowing through the valve. Insertion of a medical implement pushes down on the rigid plug, which moves the piston from an uncompressed position to a compressed position in which fluid is allowed to flow

through passageways in the valve.

Braun's argument that the rigid plug, not the piston, obstructs fluid flow through the valve is not supported by the evidence. In the Ultrasite valve, the fluid path is around the outside of the piston assembly, not through it. Even without the rigid plug, the piston bears against the housing wall near the valve opening and at the piston shoulder, blocking the passageways that allow fluid to flow through the valve. Although the piston component is hollow, a fluid barrier exists at the base where the piston is compressed between the luer nut and the housing wall. So even without a rigid plug, the piston obstructs fluid flow.

Moreover, Braun's contention that the piston or flexible element alone must obstruct fluid flow through the Ultrasite valve is not what the claim requires. Claim 1 is a "comprising" claim for "a medical valve ... comprising ... a flexible element ... [that] obstructs fluid flow...." A claim that incorporates the term "comprising" is "generally understood to signify that the claims do not exclude the presence in the accused apparatus ... of factors in addition to those explicitly recited." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 811-12 (Fed.Cir.1999) (reversing summary judgment of non-infringement where accused device included features in addition to elements claimed in a "comprising" claim); *see also Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed.Cir.1991) (a claim "which uses the term 'comprising,' is an 'open' claim which will read on devices which add additional elements"). "The signal 'comprising' implements the general rule that absent some special circumstance or estoppel which excludes the additional factor, infringement is not avoided by the presence of elements ... in addition to those specifically recited in the claim." *Vivid Techs.*, 200 F.3d at 811.

Here, Braun cannot escape infringement by pointing to other elements in the Ultrasite valve such as the rigid plug that also obstruct fluid flow. There are no special circumstances and Braun has not pointed to anything in the '673 prosecution history that would allow it to evade the general rule that an accused infringer cannot escape infringement by pointing to elements in his device that are in addition to those elements in the claimed invention. *See id.* Braun's Ultrasite valve infringes despite the fact that the piston component is not the only element obstructing fluid flow through the valve.

c. "A wall flexing to accommodate axial compression"

*7 The Ultrasite valve also comprises a wall that flexes to accommodate axial compression. The claim recites "a flexible element ... comprising a wall ... flexing to accommodate axial compression." Braun's argument that there can be only one wall that flexes (its entirety) in the flexible element in response to axial compression is not what the claim requires. The claim describes a flexible element that comprises or includes "a wall" that flexes in response to axial compression, but may also include other parts that do not flex in response to axial pressure.[FN3] The claim should not be read to require that the entire piston must flex to accommodate axial compression. *See Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 987 (Fed.Cir.1988) ("Where a specification does not *require* a limitation, that limitation should not be read from the specification into the claims.").

FN3. As ICU correctly notes, the use of the indefinite article "a" in an open-ended, "comprising" claim does not limit that claim to the singular. *KJC Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed.Cir.2000) ("This court has repeatedly emphasized that an indefinite article 'a' or 'an' in patent parlance carries the meaning of 'one or more' in open-ended claims containing the transitional phrase 'comprising.' ").

Here, the piston component is the flexible element. Inserting a syringe or other medical implement moves the piston into a compressed position and causes the piston skirt to flex in response to axial pressure. Accordingly, the piston skirt is *a wall* that flexes to accommodate axial compression of the piston, and satisfies the claim limitation.

d. "An end fitting against a ring shaped support"

Claim 1 of the '673 patent also requires that the flexible element has an "end fitting against a ring shaped support." In its claim construction, the Court found the term "ring shaped support" to be unambiguous. Markman Order at 11. In the Ultrasite valve, the piston component sits on top of the Luer nut, which makes up the bottom part of the body of the housing. Braun contends that the Luer nut presents nothing more than "a flat surface on which the piston assembly sits" and cannot constitute a

"ring shaped support." Braun's Opposition Memorandum at 20. The top surface of the Luer nut, however, is not flat. The "annular sealing ring" on the face of the Luer nut includes a concentric series of ring-shaped ridges. The piston plainly fits against a ring-shaped support, which helps to secure the piston in the housing body, and satisfies the claim limitation.

e. "At least a portion ... of the wall ... being tapered"

The final limitation of claim 1 requires that a portion of the wall of the flexible element be "tapered" between the second and third diameters. The parties agree that "tapered" means "to make gradually diminished in width toward one end." Braun's Opposition Memorandum at 21. ICU asserts that the skirt of the piston component in the Ultrasite valve satisfies this limitation.

Braun does not refute the assertion that its unmodified Ultrasite valve meets the "taper" limitation. Indeed, the valve contains a slight taper along the skirt of the piston component. Braun states that the taper is a draft mold, or a well-known non-functional by-product of the manufacturing process. Nevertheless, the piston skirt gradually diminishes in width towards one end of the Ultrasite valve structure as the claim requires.

*8 Braun contends, however, that to the extent a slight mold draft on the unmodified valve could be considered a taper, Braun has now removed it from the Ultrasite product. The piston component of the newly modified valve is no longer tapered. Instead, the piston skirt consists of straight walls. The question of whether the new, modified Ultrasite valve infringes the '673 patent is considered further below.

As to the unmodified Ultrasite valve, Braun has failed to raise any material issue of fact to rebut ICU's showing that it contains each limitation of claim 1 of the '673 patent. Consequently, the Court finds that the accused unmodified Ultrasite valve literally infringes claim 1 of the '673 patent.

2. Claim 2 of the '673 patent

Claim 2 of the '673 patent incorporates all the limitations in claim 1 and adds that an end of the flexible element in its uncompressed position near the opening must be "substantially flat." The lip of the Ultrasite valve's piston component is substantially flat. Braun contends, however, that "the end of the piston that is closest to the opening is substantially open, not flat." Braun's Opposition Memorandum at 23. But claim 2 does not require the end of the piston component to be both flat and disc-shaped as opposed to ring-shaped. Therefore, the Court finds that the accused unmodified Ultrasite valve literally infringes claim 2 of the '673 patent.

3. Claim 3 of the '673 patent

Claim 3 of the '673 patent incorporates all the limitations in claim 1 and adds that an end of the flexible element in its uncompressed position must be "substantially flush with the opening of said cavity of said body." ICU contends that "substantially" is a modifier implying "approximately" rather than "perfect." ICU's Reply Memorandum at 12; *see also* *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1368-69 (Fed.Cir.2004) (noting that the term "substantial" is a modifier implying "approximate," rather than "perfect"). But the Ultrasite valve's piston component is not even "approximately" flush with valve opening. Instead, it is recessed in the cavity of the valve near the opening. The lip of the piston component sits beneath the rigid plug, which in turn sits below the top surface of the valve opening. Therefore, the Court finds that the Ultrasite valve does not literally infringe claim 3 of the '673 patent.

4. Claim 5 of the '673 patent

Claim 5 of the '673 patent incorporates all the limitations in claim 1 and adds that the flexible element must comprise "a single molding." The parties agree that "comprises a single molding" means "formed from a single mold." Markman Order at 13. The Ultrasite piston component is molded as a single piece, which satisfies the claim limitation. Therefore, the Court finds that the Ultrasite valve literally infringes claim 5 of the '673 patent.

5. Claim 6 of the '673 patent

Claim 6 of the '673 patent incorporates all the limitations in claim 1 and adds that the valve must further comprise of "a rigid member positioned within the flexible element and to assist in maintaining the flexible element along an axial centerline when the flexible element moves between the uncompressed position and the compressed position." The rigid plug in the Ultrasite valve

satisfies this claim limitation. The rigid plug is made of a hard plastic, sits within the piston component, and prevents the piston assembly from bending when it is axially compressed. Braun contends that ICU undermines its infringement arguments regarding claim 1 because the piston component cannot be a "flexible element" if the rigid plug satisfies the "rigid member" limitation. This argument has already been rejected by the Court in its discussion of infringement of claim 1. Therefore, the Court finds that the unmodified Ultrasite valve literally infringes claim 6 of the '673 patent.

III. INFRINGEMENT OF THE '673 AND '204 PATENTS BY THE ULTRASITE VALVE WITH MODIFIED PISTON

***9** The '673 patent requires, among other things, a medical valve comprising a "flexible element" having at least three "external diameters," with "at least a portion of the outer surface of the wall of the flexible element between the second diameter and the third diameter being tapered." Similarly, the '204 patent requires a "resilient seal element" having "at least two generally arcuate segments" with "at least one segment proximate to said bottom end having a larger maximum diameter than a second segment nearer to said top end of said element." The claim limitation requiring different-sized maximum diameters was added during prosecution of the '204 patent, and ICU has asserted that this created a "taper" limitation.

Braun does not refute the assertion that its unmodified Ultrasite valve contains a slight taper in the skirt of the piston component. Instead, it contends that the newly modified Ultrasite piston is straight-walled and cannot satisfy the "taper" limitation. In September and October of 2004, Braun modified the molds used to make the piston component to eliminate any mold draft. As a result, the modified piston component used in Ultrasite valves being manufactured today has straight walls. Braun has removed the alleged "taper" from the Ultrasite product, and now moves for summary judgment that the Ultrasite valve with modified piston does not infringe claims 1-6 of the '673 patent and claims 1-5 of the '204 patent.

A. Subject Matter Jurisdiction

Contrary to ICU's assertions, the Court has jurisdiction to decide Braun's summary judgment motion of non-infringement of the '673 and '204 patents by the Ultrasite valve with modified piston.

Under the Declaratory Judgment Act, a federal court may exercise jurisdiction over a matter only in "a case of actual controversy." 28 U.S.C. § 2201(a). The courts are forbidden from rendering advisory opinions. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed.Cir.1988). The test for determining whether an "actual controversy" exists involving patents is objective and two-pronged. First, an alleged infringer must have a reasonable apprehension that the patent holder will initiate suit if the party continues the allegedly infringing activity. Second, the alleged infringer must have either produced the device or have prepared to produce that device. *Id.* at 735-36.

Although subject matter jurisdiction is decided at the time of filing, once it has been established, a court may adjudicate all those claims and related defenses brought by the parties throughout the litigation as long as an "actual controversy" continues to exist. *See Preiser v. Newkirk*, 422 U.S. 395, 401, 95 S.Ct. 2330, 45 L.Ed.2d 272 (1975) ("The rule in federal cases is that an actual controversy must be extant at all stages of review, not merely at the time the complaint was filed"). For this reason, plaintiffs do not need to file a new action on the same patent for each modification made to an accused product during the course of litigation. Notably, the modified Ultrasite valve is not a new valve but a modification to one component of the same valve.

***10** The Court has jurisdiction over the newly modified Braun Ultrasite valve. In its Complaint, ICU generically alleges that Braun is infringing the '673 and '204 patents "by making, using, offering for sale, and selling within the United States Braun's *Ultrasite needleless medical connectors.*" First Amended Complaint at ¶ 7 (emphasis added). The newly-modified Ultrasite valve is essentially the same product ICU has accused of infringement in its Complaint, except the elastomeric piston component no longer has the non-functional mold draft that ICU alleges satisfies the "taper" limitation. In addition, ICU identifies in its Infringement Disclosures Braun's Ultrasite valve product family as "accused instrumentalities," including any future ones it may find in discovery: "ICU anticipates identifying additional infringing B.Braun Ultrasite Needle-Free Valve products after conducting discovery in this matter." [FN4] ICU's 3/31/04 Amended Initial Disclosure of Asserted Claims Under Patent L.R. 3-1.

> FN4. Further, ICU seeks damages on sales during the litigation and an injunction against future sales. These remedies cannot be decided without first determining whether the Ultrasite valves with modified piston infringe the '673 and '204 patents, because Braun does not make any more Ultrasite valves with unmodified pistons for sale in the United States.

Moreover, jurisdiction exists under Braun's declaratory counterclaim that its generic "Ultrasite needleless medical connectors" do not infringe the '673 patent. Braun's 3/5/04 Answer and Counterclaims at 12. An actual controversy existed at the time of filing because the parties were already in litigation over the Ultrasite valve product family, and Braun was making and selling the accused devices. *See* Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 96, 113 S.Ct. 1967, 124 L.Ed.2d 1 (1993) ("If ... a party has actually been charged with infringement of the patent, there is, *necessarily,* a case or controversy adequate to support jurisdiction of a complaint, or a counterclaim under the Act."). Braun's decision to modify the molds used to manufacture the piston component and remove the alleged "taper" in the piston skirt did not divest the court of its jurisdiction over Ultrasite needleless medical connectors.

Jurisdiction over the newly modified Ultrasite valve also exists because Braun had a reasonable apprehension that ICU would initiate suit because it was already litigating the action and ICU had not stipulated to non-infringement by the Ultrasite valve with modified piston. The evidence also shows that all the molds used to make pistons for Ultrasite products for sale in the United States were changed by October 2004, and valves with modified pistons were being commercially sold and used by customers. Even if Braun had only switched the molds but was not yet selling the modified valve to customers, an actual controversy still exists because Braun had prepared to produce the Ultrasite valve with modified piston. *See* Int'l Med. Prosthetics Research Assocs., Inc. v. Gore Enter. Holdings, Inc., 787 F.2d 572, 575 (Fed.Cir.1986) ("[T]he statutory requirement is satisfied when ... the plaintiff has 'actually produced the accused device' *or* has 'prepared to produce such a device.' ") (emphasis added).

It is not necessary for ICU to make any allegations regarding the redesigned product in order for the Court to have jurisdiction over the Ultrasite valve with modified piston. Jurisdiction existed when ICU filed the infringement action against generic Ultrasite valves, and continues to the present day. There is no heightened pleading standard for identifying specific modifications for accused products in infringement actions. *See* Fed.R.Civ.P. 9 (specifying the claims and defenses that require pleading with particularity).

***11** ICU's reliance on Laitram Corp. v. Cambridge Wire Cloth Co., 919 F.2d 1579 (Fed.Cir.1990), is misplaced. Although the court in *Laitram* vacated summary judgment of non-infringement for lack of jurisdiction because the motion addressed products never accused of infringement, the facts are distinguishable from this case. There, the Federal Circuit was concerned with the *complete absence* of an accused product. Laitram, 919 F.2d at 1580 ("[T]he present record contains no evidence that any product accused of infringement had been made, used, or sold when the complaint was filed."). The only products before the district court when it granted summary judgment were the non-accused "possible constructions" of the product. *Id.* at 1581. Consequently, the Federal Circuit held that there was no true case or controversy. *Id.* ("In its motion, [plaintiff] was effectively and improperly saying to the district court, 'if we make and sell any of these four "possible constructions" please advise that we won't infringe.' Federal Courts do not sit, however, to decide hypotheticals or to issue advisory opinions."). In contrast, the accused Braun Ultrasite valves with modified piston are being made, used, and sold. Moreover, the Ultrasite valve with modified piston was not merely a "possible construction" of the product. By the end of 2004, Braun had modified the molds used to produce the piston component for all the Ultrasite valves manufactured and sold in the United States.

ICU also relies on Field Container Co., L.P. v. Somerville Packaging Corp., 842 F.Supp. 338 (N.D.Ill.1994). The facts in *Field Container* are also inapposite to this case. There, the court found that the plaintiff in a declaratory judgment action failed to satisfy the burden of demonstrating an actual controversy. *Id.* at 342-43. A letter threatening legal action sent to the plaintiff could not establish a reasonable apprehension of suit because it referenced an older version of the product that was "significantly different" from the version then being produced by the plaintiff. *Id.* at 342 ("We are therefore unwilling to apply the transitive property and convert any 'reasonable apprehension of suit' with respect to Version 1 to a 'reasonable apprehension of suit' with

respect to Version 2."). Consequently, the court had no jurisdiction over the product at issue. In contrast, the difference between Braun's two Ultrasite valves is not substantial enough to bar a reasonable apprehension of suit with respect to the modified Ultrasite valve when ICU initiated its litigation against Braun's unmodified valve. Indeed, the two versions of the valve are almost identical. The mold draft on the piston component was a by-product of the manufacturing process, not a functional attribute of the product. Its removal did not alter the function or operation of the valve. Thus, it was reasonable for Braun to fear being sued for infringement if it manufactured the modified valve, particularly in light of ICU's refusal to stipulate to non-infringement by the Ultrasite valve with modified piston. Braun satisfied its burden to demonstrate that an actual controversy exists, and the Court has jurisdiction to consider whether the Ultrasite valve with modified piston infringes the '673 and '204 patents.

B. Non-Infringement

***12** The Court now turns to the merits of Braun's summary judgment motion with respect to the Ultrasite valve with modified piston. Both the '673 and '204 patents recite a medical valve containing a tapered structure. The parties agree that "tapered" means "to make gradually diminished in width toward one end." Braun's Opposition Memorandum at 21.

ICU asserts that the skirt of the piston component in Braun's Ultrasite valve satisfies this limitation. As to the Ultrasite valve with modified piston, Braun has now removed the alleged "taper" from the product. The piston skirt no longer gradually diminishes in width towards one end. Design drawings of the modified piston component show that the piston is no longer tapered. The piston skirt now consists of straight walls. Notably, even ICU does not contend that the modified Ultrasite product infringes (either literally or by virtue of the doctrine of equivalents) the '673 and '204 patents.

Thus, there is no genuine dispute that the modified Ultrasite valve does not infringe the '673 and '204 patents, and the Court grants Braun's motion for summary judgment of non-infringement by the Ultrasite valve with modified piston.

IV. INEQUITABLE CONDUCT

Braun has alleged in its pleadings that ICU's '673 patent is unenforceable because of the inequitable conduct of ICU during the prosecution of the '673 patent before the Patent and Trademark Office ("PTO").

Specifically, Braun argues that ICU committed inequitable conduct by failing to disclose the existence of this ongoing litigation and relevant litigation materials regarding infringement by the Ultrasite valve to the '673 patent examiner, while simultaneously prosecuting a new patent application with a petition alleging infringement by the same Ultrasite valve.

The '673 patent application was filed as a continuation of an abandoned application originally filed in December 1991. The inventor, Dr. George Lopez, [FN5] successfully petitioned for an expedited examination of the application based on the alleged infringement of the new invention by Braun's Ultrasite valve. The petition did not disclose that the assignee of the '673 patent, ICU, had already been in litigation with Braun over the same Ultrasite valve for over a year. It also failed to inform the PTO that ICU alleged in the ongoing litigation that the same Ultrasite valve infringed the '204 patent-a patent that shares the same specification as the '673 patent.

FN5. Dr. Lopez is also the inventor of the '204 patent and the Chief Executive Officer of plaintiff ICU Medical, Inc.

ICU, however, contends that there is no evidence of inequitable conduct on its part as to the prosecution of the '673 patent. ICU points out that the PTO was notified by the Clerk of the United States District Court for the Northern District of California as to the pending litigation involving the '048 and '673 patents pursuant to 35 U.S.C. § 290. Moreover, ICU disclosed all relevant prior art, including every prior art patent raised during the course of litigation,[FN6] to the PTO during the '673 prosecution in accordance with the applicable regulations. ICU argues that there is no evidence of any intent on its part to deceive or mislead the PTO.

FN6. The list of relevant prior art references raised during the course of litigation and disclosed by ICU to the PTO include: Armao (U.S. Patent No. 3,134,380), Adams (U.S. Patent No. 2,847,995), Vailancourt (U.S. Patent No. 4,512,766), DeFrank (U.S.

Patent No. 5,242,432), Cambio (U.S. Patent No. 4,201,208), and Lopez (U.S. Patent No. 4,782,841).

***13** The Court finds that the existence of this ongoing litigation was material to the '673 patent prosecution, and that ICU failed to disclose this information to the '673 patent examiner. There is also sufficient evidence to raise a genuine issue of triable fact as to whether ICU failed to disclose this ongoing litigation with the intent to mislead or deceive the PTO. Consequently, summary judgment in favor of ICU with respect to Braun's affirmative defense of inequitable conduct as to the '673 patent is not appropriate.

A. Applicable Law

A patent applicant's duty to disclose material information to the PTO arises under the general duty of candor, good faith, and honesty as set forth in 37 C.F.R. § 1.56(a), which states, in part:
Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.

37 C.F.R. § 1.56(a).

The Manual of Patent Examining Procedure ("MPEP") further provides:
Where the *subject matter* for which a patent is being sought is or has been involved in litigation, *the existence of such litigation and any other material information arising therefrom* must be brought to the attention of the Patent and Trademark Office; such as, for example, evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of 'fraud,' 'inequitable conduct,' or violation of duty of disclosure. Such information might arise during litigation in, for example, pleadings, admissions, discovery including interrrogatories, deposition, and other documents, and testimony.

MPEP § 2001.06(c) (emphasis added). Although MPEP § 2001.6(c) is not binding law, it sheds light on the PTO's official interpretation of 37 C.F.R. § 1.56(a) regarding the materiality of related litigation.

A patentee commits inequitable conduct if, "during prosecution of the application, he makes an affirmative representation of material fact, fails to disclose material information, or submits false material information, and does so with intent to deceive." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1358 (Fed.Cir.2003) (citation omitted). To find inequitable conduct, there must be clear and convincing evidence that both the materiality and intent prongs of the test are satisfied. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233 (Fed.Cir.2003).

1. Sufficiency of § 290 Notice

ICU contends that the ongoing litigation relating to infringement by the Ultrasite valve was properly disclosed and brought to the attention of the PTO when the Clerk gave notice of this litigation pursuant to 35 U.S.C. § 290. [FN7]

FN7. 35 U.S.C. § 290 provides:
The clerks of the courts of the United States, within one month after the filing of an action under this title shall give notice thereof in writing to the Director, setting forth so far as known the names and addresses of the parties, name of the inventor, and the designating number of the patent upon which the action has been brought.... The Director shall, on receipt of such notices, enter the same in the file of such patent.

The duties imposed by 37 C.F.R. § 1.56(a) and MPEP § 2001.06(c) cannot be supplanted by the general administrative notice required by Section 290. The patent applicant has an independent duty to disclose the existence of related patent infringement litigation to the PTO examiner. The duty of disclosure is particularly important in the context of patent prosecutions, which are conducted before an examiner in the absence of any represented adversary. In *ex parte* patent prosecutions, PTO examiners rely on the patent applicants to make full disclosure of material information of which they are aware in each case. *See Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 147 (D.Mass.2001) ("[T]he duty of candor ultimately falls on the shoulders of the patent applicant...."). Moreover, the PTO has hundreds of examiners who handle hundreds of thousands of applications annually, and one examiner is unlikely to be aware of the status or assertions that an applicant makes to another examiner.

***14** Here, for example, although the Section 290 notice was sent to the PTO Director on the day the ongoing patent infringement action was filed, the PTO was directed under Section 290 to file the notice in the '204 and '048 patent file histories. Any Section 290 notice would not go to the examiner of the subsequent '673 patent application-a different, but related patent application. Indeed, the Section 290 notice appears nowhere in the '673 file history. As a result, the '673 patent examiner was unaware of this Court's claim constructions on similar language from the '204 and '048 patents. The '673 patent examiner was never told about Braun's invalidity contentions. The '673 patent examiner was never shown *any* of the pleadings or documents in this litigation. Consequently, ICU cannot rely on Section 290 to satisfy its duty to disclose the existence of related litigation to the '673 patent examiner.

In fact, the PTO advises that "the individuals covered by 37 C.F.R. 1.56 cannot assume that the examiner of a particular application is necessarily aware of other applications which are 'material to patentability' of the application in question, but must instead bring such other applications to the attention of the examiner." MPEP § 2001.6(b).[FN8] Likewise, an applicant cannot assume that an examiner, however diligent and well-informed, will be aware of Section 290 notices in other patents. To do so would effectively eviscerate the duty of disclosure regarding related litigation owed to each patent examiner.

> FN8. Furthermore, applicants should "continue to submit information for consideration by the Office in applications rather than making and relying on their own determinations of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive." *Critikon,* 120 F.3d at 1257.

2. Materiality

Information must be disclosed to the PTO when it is material to patentability. Materiality is not limited to prior art but includes "any information that a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent. *Bristol-Myers,* 326 F.3d at 1234. According to the PTO, information is material to patentability if:
It is not cumulative to information already of record [in the application], and
(1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
(2) It refutes, or is inconsistent with, a position the applicant [has taken] in:
(i) Opposing an argument of unpatentability relied on by the [PTO], or
(ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b).

In fact, related litigation is material *per se. See* MPEP § 2001.06(c) (stating that "the existence of such litigation *and any other* material arising therefrom" is material); *see also Daimlerc hrysler AG v. Fueling Advanced Techs., Inc.,* 276 F. Supp 2d 1054, 1063 (S.D.Cal.2003). Failure to disclose related litigation may lead to a finding of inequitable conduct. *See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.,* 120 F.3d 1253, 1255-59 (Fed.Cir.1997); *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.,* 68 F.Supp.2d 508, 550-51 (D.N.J.1999) (denying patentee's preliminary-injunction motion because accused infringer had substantial defense of inequitable conduct based on patentee's failure to disclose materials from a related litigation to the examiner).

***15** The materiality of the '204 and '048 patent litigation which challenged both the validity and enforceability of the subject matter of the '673 application is obvious. Indeed, even ICU does not dispute that this ongoing litigation was material to the '673 patent prosecution. ICU Brief at 5-6. The '204 patent shared the same specification and disclosed the same subject matter as the '673 application. Braun also raised invalidity contentions against the patents-in-suit and alleged inequitable conduct against ICU in connection with its prosecution of the '048 patent, which may have been material to patentability of the '673 application. *See* MPEP § 2001.6(c) ("Examples of [ ]material information include ... allegations of 'fraud,' 'inequitable conduct,' and 'violation of duty of disclosure.' ").

3. Intent

As a general principle, the requirements of materiality and intent are inversely proportional. *See Critikon,* 120 F.3d at 1257. "A lesser quantum of intent is necessary when the omission or misrepresentation is highly material, and vice versa." *Diamlerchrysler,* 276 F.Supp.2d at 1065 (quoting

Amgen, 314 F.3d at 1358). Nevertheless, the intent to deceive or mislead cannot be inferred solely from the materiality of the omission. *Amgen*, 314 F.3d at 1358. Proof of intent to mislead may be shown by circumstantial evidence. *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1189-90 (Fed.Cir.1993) (" '[S]moking gun' evidence is not required in order to establish an intent to deceive.... Rather, this element of inequitable conduct, must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct.") (citation omitted).

A relatively high degree of intent may be demonstrated from the facts of this case. ICU was clearly aware that the subject matter of the pending litigation was material to the '673 patent prosecution. It knew that the claims of the '673 patent "read on" Braun's Ultrasite valve because it specifically alleged infringement by the Ultrasite valve in a Petition to Make Special to expedite examination of the '673 patent. Braun suggests that ICU's effort to obtain the '673 patent in time for use in this litigation provided a significant incentive for ICU to hide this litigation from the PTO examiner. [FN9]

> FN9. Indeed, disclosing the ongoing litigation may have forced ICU to address their various positions during litigation and consequently delayed the '673 patent prosecution by raising relevant invalidity defenses and material prior art.
> For example, the PTO examiner may have asked for more information regarding ICU's claim construction arguments that the '204 patent claims, which share the same specification as the '673 application, required a "taper" on the "resilient seal element" even if that term is never used. ICU relied on this "taper" limitation in opposing Braun's summary judgment motion for patent invalidity. Although the PTO examiner never had the opportunity to consider this information, ICU subsequently added an express "taper" limitation to the application claims of the '673 patent before it issued.

During the prosecution of the '673 application, ICU also objected to Braun's motion to compel production of pending ICU patent applications that were related to the '204 patent. ICU repeatedly told Magistrate Judge James that the applications were not "relevant," despite having already filed a Petition to Make Special alleging infringement by the same Ultrasite valve. This made it impossible for Braun to inform the '673 patent examiner of the pending litigation.

Put another way, ICU may have been trying to hide the pending litigation from the '673 patent examiner while simultaneously using the alleged infringement by the Ultrasite valve as a reason to expedite issuance of the '673 patent, which ICU could then use as a weapon in the ongoing litigation.

***16** ICU's reliance on *Haney v. Timesavers, Inc.*, 900 F.Supp. 1378, 1382 (D.Or.1995) (stating that "the court cannot infer an intent to deceive ... from the manner in which the information was conveyed to the Patent Office when the information was, in fact, conveyed.") is misplaced. In *Haney*, the district court found insufficient evidence to infer an intent to deceive and sustain an inequitable conduct claim. *Id.* Here, however, there is substantial evidence from which the Court could find that ICU had the intent to deceive the PTO regarding ongoing litigation surrounding the Ultrasite valve. ICU's failure to disclose the existence of this ongoing litigation regarding infringement by the Ultrasite valve to the '673 patent examiner, as well as the existence of the '673 application during discovery, while simultaneously prosecuting a new patent application with a petition alleging infringement by the same valve, raises a genuine issue of triable fact as to inequitable conduct.

CONCLUSION

For the reasons stated above, the Court hereby resolves the motions as follows:
1. ICU's motion for summary judgment that Braun's Ultrasite valve infringes the '673 patent is GRANTED in part as to claims 1-2 and 5-6, and DENIED in part as to claim 3.
2. Braun's motion for summary judgment that the Ultrasite valve does not infringe the '673 patent is DENIED in part as to claims 1-2 and 4-6, and GRANTED in part as to claim 3.
3. Braun's motion for summary judgment that the Ultrasite valve with modified piston does not infringe the '673 and '204 patents is GRANTED.
4. ICU's motion for summary judgment of no inequitable conduct is DENIED.

It is further ORDERED that trial on the issue of inequitable conduct shall begin on April 11, 2005 at

8:30 a.m. A pretrial conference shall be held on March 31, 2005 at 2:30 p.m.

IT IS SO ORDERED.

N.D.Cal.,2005.
ICU Medical, Inc. v. B.Braun Medical Inc.
Not Reported in F.Supp.2d, 2005 WL 588341 (N.D.Cal.)

Briefs and Other Related Documents (Back to top)

- 2004 WL 4054319 (Trial Pleading) Revised Joint Claim Construction and Prehearing Statement for '673 Patent (Aug. 27, 2004)
- 2004 WL 4054318 (Trial Pleading) Braun's First Answer and Counterclaims to ICU's First Amended Complaint (Mar. 5, 2004)
- 2002 WL 33802688 (Trial Motion, Memorandum and Affidavit) Braun's Memorandum of Points and Authorities in Support of Its Motion for Summary Adjudication on the Priority Date of the '048 Patent (Aug. 2, 2002)
- 2002 WL 33802685 (Trial Motion, Memorandum and Affidavit) Braun's Motion and Memorandum of Points and Authorities in Support to Compel the Production of Certain Patent Applications and Prosecution Histories and Information Related Thereto (Jul. 26, 2002)
- 2002 WL 33802686 (Trial Motion, Memorandum and Affidavit) Braun's Motion and Memorandum of Points and Authorities in Support to Compel ICU to Respond to Braun's Interrogatory No. 4 (Jul. 26, 2002)
- 2002 WL 33802687 (Trial Motion, Memorandum and Affidavit) Braun's Motion to Compel and Memorandum of Points and Authorities in Support of Its Motion to Compel Production of ICU's Privilege Log and Documents That Have Been Improperly Redacted (Jul. 26, 2002)
- 2002 WL 33802684 (Trial Motion, Memorandum and Affidavit) Plaintiff ICU Medical, Inc.'s Opening Brief on Claim Construction (Jul. 5, 2002)
- 2002 WL 33802689 (Trial Pleading) First Amended Answer and First Amended Counterclaims (Jan. 10, 2002)
- 2001 WL 35709537 (Trial Motion, Memorandum and Affidavit) Plaintiff ICU Medical, Inc.'s Reply Memorandum in Support of Motion to Dismiss Counterclaims and Strike Defenses of B. Braun Medical, Inc. (Nov. 30, 2001)
- 2001 WL 35709536 (Trial Motion, Memorandum and Affidavit) B. Braun Medical Inc.'s Opposition to ICU Medical, Inc.'s Motion to Dismiss Counterclaims and to Strike Defenses (Nov. 26, 2001)
- 2001 WL 35709535 (Trial Motion, Memorandum and Affidavit) Plaintiff ICU Medical, Inc.'s Notice of Motion, Motion to Dismiss Counterclaims and Strike Defenses of B. Braun Medical, Inc.'s Answer and Counterclaim, and Memorandum of Points and Authorities in Support of Motion to Strike and Dismiss (Oct. 30, 2001)
- 2001 WL 35709538 (Trial Pleading) Complaint for Patent Infringement (Aug. 21, 2001)
- 3:01cv03202 (Docket) (Aug. 21, 2001)

END OF DOCUMENT

EXHIBIT Y

Briefs and Other Related Documents
Only the Westlaw citation is currently available.
United States District Court,D. Arizona.
RESEARCH CORPORATION TECHNOLOGIES, INC., Plaintiff,
v.
MICROSOFT CORPORATION, Defendant.
No. CV-01-658-TUC-MLR.

May 22, 2006.

Stephen J. Joncus (OSB # 01307), Todd M. Siegel (OSB # 00104), John D. Vandenberg (OSB # 89375), Garth A. Winn (OSB # 92158), Klarquist Sparkman, LLP, Portland, Oregon, Jeffrey Willis (# 004870), Andrew Jacobs (# 021146), Adrienne Ehrhardt (# 022429), Snell & Wilmer, L.L.P ., Tucson, Arizona, Stephen McGrath, Microsoft Corporation, Redmond, Washington, for Defendant Microsoft Corporation.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DECLARING RCT'S PATENTS UNENFORCEABLE FOR INEQUITABLE CONDUCT

REAL, J.

*1 This matter having been set for trial to determine the issue of inequitable conduct, witnesses having been sworn, evidence having been presented and each party having been duly heard, the Court hereby enters the following findings and conclusions pursuant to Fed.R.Civ.P. 52, further to its findings and conclusions stated in Court.

1. The contemporaneous test results and reports of Kevin J. Parker and Theophano Mitsa characterizing those test results directly contradict the performance claims of the 1990 and 1991 Parker/Mitsa patent applications. The "visually pleasing" results promised in the applications are directly contradicted by the "visually annoying" and "Graininess: Yes" results reported by Parker/Mitsa to their peers.

2. Information is material if "a reasonable examiner would be substantially likely to consider [it] important in deciding whether to allow an application to issue as a patent." *Bristol-Myers Squibb Co. v. Rhone-Poulence Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed.Cir.2003). A reasonable Patent Examiner clearly would have considered the test results, Parker/Mitsa's reported rejection of the applications' disclosed algorithm, and Parker/Mitsa's reported adoption of a technique that was inconsistent with the applications, each important to at least the written description and enablement requirements for patentability.

3. Based on the clear and convincing evidence presented at trial, including that identified in Exhibits 1640-41, 1643-46, 1648, 1650, 1655, and 1657-59, the Court finds the withheld information to be highly material to the 1990, 1991, and 1994 applications, under both the prior and the current Rule 56 materiality standards.

4. The facts established at trial compel a conclusion that Parker/Mitsa each knew, and certainly should have known, of the high materiality of the information they withheld from the PTO. Parker/Mitsa knew that their claim to patentability was based primarily on their claim that their disclosed algorithm produced visually pleasing, non-clumpy images that lacked low-frequency graininess at every level of gray. (*See, e.g.,* August 12th TR at 74:23-75:21.) It is not credible that they did not know that a reasonable Examiner would consider it important to know that the patent applicants' reported efforts to practice the applications' disclosed No K technique had led to "visually annoying clumps," not the "visually pleasing" images promised by the patent applications and their patent claims. Based on the compelling evidence of Parker/Mitsa's knowledge of high materiality, the Court finds a strong inference of an intent by Parker/Mitsa to mislead the Patent Office.

5. For the above reasons, and those set forth in my oral Findings, I find that Parker/Mitsa acted with an intent to mislead and deceive the Patent Office when they withheld this highly material information.

6. Having closely observed both Parker/Mitsa testify, I have been able to evaluate and consider their credibility. In this regard I find that Parker was not credible, and Mitsa was evasive, on many key points in their testimony. This is based, in large part, upon my personal observation of their demeanor while testifying. This lack of credibility and evasiveness of Parker/Mitsa is further demonstrated in Exhibits 1655-71, and further supports my above findings on their intent to mislead the Patent Office.

*2 7. In my findings, I have not resolved any factual disputes necessary for determination of patent invalidity, patent infringement, or any other jury issue.

8. In the exercise of its discretion, and having weighed its findings of materiality and intent to deceive the PTO, the Court concludes that Parker/Mitsa committed inequitable conduct in procuring the '310, '228, and '305 patents. As a result, the '310, '228 and '305 patents are unenforceable.

D.Ariz.,2006.
Research Corp. Technologies, Inc. v. Microsoft Corp.
Slip Copy, 2006 WL 1544381 (D.Ariz.)

Briefs and Other Related Documents (Back to top)

• 2005 WL 2835363 (Trial Motion, Memorandum and Affidavit) Research Corporation Technologies, Inc.'s Objections to Microsoft's (Proposed) Findings of Fact and Conclusions of Law Declaring Rct's Patents Unenforceable for Inequitable Conduct (Sep. 13, 2005) Original Image of this Document (PDF)
• 4:01cv00658 (Docket) (Dec. 21, 2001)

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